

**What is claimed is:**

1. An excisional biopsy system, comprising:

a tubular member including a proximal end and a distal end, the tubular member defining a first window near the distal end, and

5 a first removable probe that includes a proximal portion including cutting tool extending means, a distal portion and a cutting tool near the distal portion, the first removable probe being configured to fit at least partially within the tubular member to enable the cutting tool to selectively bow out of and to retract within the first window when the cutting tool extending means are activated.

10 2. The excisional biopsy system of Claim 1, wherein the first removable probe further includes a window slide and wherein the proximal end further includes a window slide extending means, the window slide being configured to selectively cover a portion of the first window when the window slide extending means are activated.

15 3. The excisional biopsy system of Claim 1, wherein the cutting tool includes one of a ribbon sharpened on a leading edge thereof and a wire.

4. The excisional biopsy device of Claim 1, wherein the cutting tool includes an RF cutting tool and wherein the first removable probe is adapted to be connected to an RF power source.

20 5. The excisional biopsy system of Claim 4, wherein the cutting tool includes at least one of a monopolar and a bipolar RF cutting tool.

6. The excisional biopsy system of Claim 1, wherein the tubular member includes a first internal guide that is configured to enable the first removable probe to slide within the tubular member.

7. The excisional biopsy system of Claim 1, wherein the first removable probe  
5 includes a second internal guide, the second internal guide enabling the cutting tool to slide within the first removable probe when the cutting tool extending means are activated.

8. The excisional biopsy system of Claim 2, wherein the first removable probe includes a third internal guide, the third internal guide enabling the window slide to slide within the first removable probe when the window slide extending means are activated.

9. The excisional biopsy system of Claim 1, further including a second  
10 removable probe comprising a proximal section including a tissue collection device extending means and a distal section including a tissue collection device, the second removable probe being configured to fit at least partially within the tubular member to enable the tissue collection device to extend out of and to retract within the first window when the  
15 tissue collection device extending means are activated.

10. The excisional biopsy system of Claim 1, wherein the tubular member defines a second window near the distal end thereof, and wherein the biopsy system further includes a second removable probe comprising a proximal section including a tissue collection device extending means and a distal section including a tissue collection device, the second  
20 removable probe being configured to fit at least partially within the tubular member to enable the tissue collection device to selectively extend out of and to retract within the second window when the tissue collection device extending means are activated.

11. The excisional biopsy system of Claim 9, wherein the tissue collection device includes one of a ribbon and a wire, and a thin flexible sheet of material attached to said one of ribbon and wire, said thin flexible sheet at least partially encapsulating a tissue specimen as said one of ribbon and wire is extended and the tubular member rotated.

5 12. The excisional biopsy system of Claim 11, wherein the thin flexible sheet of material includes a bag attached to said one of ribbon and wire so as to open and close when said one of ribbon and wire is extended and retracted, respectively.

10 13. The excisional biopsy system of Claim 10, wherein the tissue collection device includes one of a ribbon and a wire, and a thin flexible sheet of material attached to said one of ribbon and wire, said thin flexible sheet at least partially encapsulating a tissue specimen as said one of ribbon and wire is extended and the tubular member rotated.

14. The excisional biopsy system of Claim 13, wherein the thin flexible sheet of material includes a bag attached to said one of ribbon and wire so as to open and close when said one of ribbon and wire is extended and retracted, respectively.

15 15. The excisional biopsy system of Claim 9, wherein the tubular member includes a first internal guide that is configured to enable one of the first and the second removable probe to slide within the tubular member until the one of the cutting tool and the tissue collection device faces out of the first window.

20 16. The excisional biopsy system of Claim 10, wherein the tubular member includes a second internal guide that is configured to enable the second removable probe to slide within the tubular member until the tissue collection device faces out of the second window.

17. The excisional biopsy system of Claim 1, wherein the distal portion of the first removable probe further includes a tissue collection device near a trailing edge of the cutting tool, the tissue collection device being configured to selectively extend out of and retract into the first window.

5 18. The excisional biopsy system of Claim 17, wherein the proximal portion of the first removable probe includes a tissue collection device extending means, the tissue collection device extending means being adapted to enable the tissue collection device to extend out of and to retract within the first window independently of the cutting tool.

10 19. The excisional biopsy system of Claim 17, wherein the tissue collection device is coupled to the cutting tool and wherein the cutting tool extending means is also configured to selectively extend the tissue collection device out of the first window and retract the tissue collection device into the first window as the cutting tool is extended and retracted, respectively.

15 20. The excisional biopsy system of Claim 19, wherein the first removable probe includes an insulator between the tissue collection device and the cutting tool.

21. The excisional biopsy system of Claim 20, wherein the insulator includes at least one of an air gap and an insulating material attached to and separating the cutting tool from the tissue collection device.

20 22. The excisional biopsy system of Claim 1, wherein the first removable probe defines at least one internal lumen that terminates near the distal portion as an opening formed in a surface of the first removable probe, the opening being adapted to deliver a pharmaceutical agent and/or to provide suction.

23. The excisional biopsy system of Claim 1, further including a third removable probe, the third removable probe being configured to fit at least partially within the tubular member and including an imaging device mounted therein.

24. The excisional biopsy system of Claim 23, the imaging device includes an  
5 ultrasound sensor.

25. The excisional biopsy system of Claim 24, wherein the ultrasound sensor includes a linear array of ultrasound transducers.

26. The excisional biopsy system of Claim 24, wherein the ultrasound sensor is disposed near a distal tip of the third removable probe and away from the cutting tool, so that  
10 the ultrasound sensor sweeps a plane ahead of the cutting tool as the tubular member rotates.

27. The excisional biopsy system of Claim 24, wherein the ultrasound sensor is tuned within a range from about 7.5 MHz to about 20 MHz.

28. The excisional biopsy system of Claim 24, wherein the ultrasound sensor is disposed within the tubular member at an angle  $\alpha$  relative to the cutting tool, the angle  $\alpha$   
15 being no smaller than that necessary to effectively control the operation of the cutting tool in response to information gathered from the ultrasound transducer as the tubular member rotates.

29. The excisional biopsy system of Claim 24, wherein the angle  $\alpha$  is less than about 90 degrees.

20 30. The excisional biopsy system of Claim 1, wherein at least one of the tubular member and the first removable probe is configured for a single use and is disposable.

31. The excisional biopsy system of Claim 9, wherein the second removable probe is configured for a single use and is disposable.

32. A soft tissue treatment method, comprising the steps of:

inserting a generally tubular member into the soft tissue, the tubular member defining  
5 a first window in a surface thereof, the tubular member being configured to accept a removable probe inserted therein;

inserting a first removable probe into the tubular member, the first removable probe including a cutting tool that is adapted to face out of the first window;

selectively activating the cutting tool to cut a tissue specimen while rotating the  
10 tubular member within the tissue;

removing the first removable probe from the tubular member while the tubular member stays in place;

inserting a second removable probe into the tubular member, the second removable probe including a tissue collection device that is adapted to face out of the first window, and

15 selectively activating the tissue collection device to encapsulate the tissue specimen while rotating the tubular member while.

33. The method of Claim 32, wherein the first removable probe is inserted into the tubular member before the tubular member is inserted into the soft tissue.

34. The method of Claim 32, further including the steps of:

20 inserting a third removable probe into the tubular member, the third removable probe including an imaging device therein that is configured to face out of the first window, and

rotating the tubular member while activating the imaging device to image the soft tissue at least one of before and after the tissue collection device is activated.

35. The method of Claim 32, wherein the tubular member defines a second window in the surface thereof and wherein the method further includes the steps of:

5 inserting a third removable probe into the tubular member, the third removable probe including an imaging device therein that is configured to face out of the second window, and rotating the tubular member while activating the imaging device to image the soft tissue at least one of before, during and after the tissue collection device is activated.

36. The method of claim 35, further comprising the steps of:

10 displaying information received from the imaging device on a display device; and varying an operation of at least one of the cutting tool and the tissue collection device during at least one of the first and second activating steps based upon the displayed information from the imaging device.

37. The method of claim 36, wherein the cutting tool comprises an electrosurgical blade and wherein the method further comprises the step of varying a power applied to the electrosurgical blade based upon information received from the imaging device or feedback to the RF generator.

38. The method of claim 32, further comprising the step of stabilizing the soft tissue in an uncompressed state prior to the first inserting step.

20 39. The method of claim 32, wherein at least one of the tubular member and the first removable probe defines an internal lumen and a plurality of through holes in fluid

communication with the internal lumen, and wherein the method further comprises at least one of the steps of:

delivering a pharmaceutical agent to the tissue via the plurality of through holes, and suctioning smoke and/or fluids from the soft tissue via the plurality of through holes.

5        40.     A soft tissue treatment method, comprising the steps of:

inserting a generally tubular member into the soft tissue, the tubular member defining a first window in a surface thereof, the tubular member being configured to accept a removable probe inserted therein;

10        inserting a first removable probe into the tubular member, the first removable probe including a cutting tool and a tissue collection device that are adapted to face out of the first window;

selectively activating the cutting tool to cut a tissue specimen while rotating the tubular member within the soft tissue, and

15        selectively activating the tissue collection device to encapsulate the tissue specimen while rotating the tubular member.

41.     The method of Claim 40, wherein the first removable probe is inserted into the tubular member before the tubular member is inserted into the soft tissue.

42.     The method of Claim 40, wherein the tubular member defines a second window in the surface thereof and wherein the method further includes the steps of:

20        inserting a second removable probe into the tubular member, the second removable probe including an imaging device therein that is configured to face out of the second window, and



rotating the tubular member while activating the imaging device to image the soft tissue at least one of before, during and after at least one of the cutting tool and the tissue collection device are activated.

43. The method of Claim 42, further comprising the steps of:

5 displaying information received from the imaging device on a display device; and

varying an operation of at least one of the cutting tool and the tissue collection device during at least one the first and second activating steps based upon the displayed information from the imaging device.

44. The method of Claim 40, wherein the cutting tool comprises an electrosurgical

10 blade and wherein the method further comprises the step of varying a power applied to the electrosurgical blade based upon information received from the imaging device and/or feedback to the RF generator.

45. The method of Claim 40, further comprising the step of stabilizing the soft tissue in an uncompressed state prior to the first inserting step.

15 46. The method of Claim 40, wherein at least one of the tubular member and the first removable probe defines an internal lumen and a plurality of through holes in fluid communication with the internal lumen, and wherein the method further comprises at least one of the steps of:

delivering a pharmaceutical agent to the tissue via the plurality of through holes, and

20 suctioning smoke and/or fluids from the soft tissue via the plurality of through holes.

47. The method of Claim 40, wherein the first and second rotating steps are carried out simultaneously and wherein the cutting tool and the tissue collection device are coupled to one another.

48. The method of Claim 40, wherein the first and second rotating steps are  
5 carried out simultaneously and wherein the cutting tool and the tissue collection device are activated independently of one another.

49. An excisional biopsy system for soft tissue, comprising:

a tubular member defining a first, a second and a third window near a distal tip thereof;

10 a first removable probe comprising a proximal portion that includes cutting tool extending means, a distal portion and a cutting tool near the distal portion, the first removable probe being configured to fit at least partially within the tubular member to enable the cutting tool to selectively bow out of and to retract within the first window when the cutting tool extending means are activated;

15 a second removable probe comprising a proximal section including a tissue collection device extending means and a distal section including a tissue collection device, the second removable probe being configured to fit at least partially within the tubular member to enable the tissue collection device to extend out of and to retract within the second window when the tissue collection device extending means are activated, and

20 a third removable probe, the third removable probe being configured to fit at least partially within the tubular member and including an imaging device mounted therein that is configured to face out of the third window.

50. The excisional biopsy system of Claim 49, wherein at least one of the tubular member, the first removable probe, the second removable probe and the third removable probe is for single use and is disposable.

51. The excisional biopsy system of Claim 49, the imaging device includes an  
5 ultrasound sensor.

52. The excisional biopsy system of Claim 51, wherein the ultrasound sensor includes a linear array of ultrasound transducers.

53. The excisional biopsy system of Claim 51, wherein the ultrasound sensor, when inserted in the tubular member is disposed ahead of a leading edge of the cutting tool,  
10 so that the ultrasound sensor sweeps a plane ahead of the cutting tool as the tubular member rotates.

54. The excisional biopsy system of Claim 51, wherein the ultrasound sensor is tuned within a range from about 7.5 MHz to about 20 MHz.

55. The excisional biopsy system of Claim 51, wherein the ultrasound sensor is  
15 disposed within the tubular member at an angle  $\alpha$  relative to the cutting tool, the angle  $\alpha$  being no smaller than that necessary to effectively control the operation of the cutting tool in response to information gathered from the ultrasound sensor as the tubular member rotates.

56. The excisional biopsy system of Claim 51, wherein the angle  $\alpha$  is less than about 90 degrees.

20 57. An excisional biopsy system for soft tissue, comprising:

a tubular member defining a first and a second window near a distal tip thereof;

a first removable probe comprising a proximal portion and a distal portion, the proximal portion including a tool extending means, the distal portion including a cutting tool and a tissue collection tool, the first removable probe being configured to fit at least partially within the tubular member to enable the cutting and tissue collection tools to selectively  
5 extend out of and to retract within the first window when the tool extending means are activated, and

a second removable probe, the second removable probe being configured to fit at least partially within the tubular member and including an imaging device mounted therein that is configured to face out of the second window.

58. The excisional biopsy system of Claim 57, wherein the cutting and tissue collection tools are mechanically coupled to one another.

59. The excisional biopsy device of Claim 57, wherein the cutting and tissue collection tools are independently activated and wherein the tool extending means includes a cutting tool extending means operative to extend and to retract the cutting tool out of and into  
15 the first window and a tissue collection extending means operative to extend and to retract the tissue collection tool into and out of the first window.

60. The excisional biopsy device of Claim 57, wherein the cutting tool includes an RF cutting tool and wherein the first removable probe is adapted to be connected to an RF power source.

20 61. The excisional biopsy system of Claim 60, wherein the cutting tool includes at least one of a monopolar and a bipolar RF cutting tool.

62. The excisional biopsy system of Claim 57, wherein at least one of the tubular member, the first removable probe and the second removable probe is for single use and is disposable.

63. The excisional biopsy system of Claim 57, the imaging device includes an  
5 ultrasound sensor.

64. The excisional biopsy system of Claim 63, wherein the ultrasound sensor includes a linear array of ultrasound transducers.

65. The excisional biopsy system of Claim 63, wherein the ultrasound sensor, when inserted in the tubular member, is disposed ahead of a leading edge of the cutting tool,  
10 so that the ultrasound sensor sweeps a plane ahead of the cutting tool as the tubular member rotates.

66. The excisional biopsy system of Claim 63, wherein the ultrasound sensor is tuned within a range from about 7.5 MHz to about 20 MHz.

67. The excisional biopsy system of Claim 63, wherein the ultrasound sensor is  
15 disposed within the tubular member at an angle  $\alpha$  relative to the cutting tool, the angle  $\alpha$  being no smaller than that necessary to effectively control the operation of the cutting tool in response to information gathered from the ultrasound sensor as the tubular member rotates.

68. The excisional biopsy system of Claim 67, wherein the angle  $\alpha$  is less than about 90 degrees.